



MECKLENBURG COUNTY  
Land Use and Environmental Services Agency  
- *AIR QUALITY* -

November 7, 2019

Mr. Jeff Maczko, General Manager  
Sterigenics US, LLC  
10821 Withers Cove Park Drive  
Charlotte, NC 28278

RE: Air Quality Permit to Construct/Operate No. 19-083-959  
Emission Reduction Project

Dear Mr. Maczko:

In accordance with your application dated August 27, 2019, Mecklenburg County Air Quality (MCAQ) forwards herewith Permit to Construct/Operate (Permit) No. 19-083-959 for the construction/operation of air pollution emission sources or abatement equipment. This permit has been amended to include changes associated with the facility's emission reduction project.

Review the Permit and attached enclosures carefully. Please note the following:

- ▶ **Facility Category:** The category for this facility is "Synthetic Minor". This category is based on the information supplied to MCAQ and is used to determine appropriate annual and application processing fees.
- ▶ This Permit maintains facility-wide emission limits for certain pollutants and a regulatory status of "Synthetic Minor" for your facility. Synthetic Minor facilities are not subject to Mecklenburg County Air Pollution Control Ordinance (MCAPCO) Section 1.5500 - "Title V Procedures" as major facilities.
- ▶ **Permit Conditions and Limitations:** This Permit contains General Conditions and Limitations, which are applicable to your facility, and Specific Conditions and Limitations, which are applicable to emission sources as identified in the Emission Source Table.
- ▶ **Monitoring and Recordkeeping:** This permit requires monitoring and recordkeeping in accordance with Specific Condition and Limitation No. S-7.
- ▶ **Performance Testing Requirements:** This permit requires performance testing of all emission sources and control devices within 180 days following installation and startup of the new control devices in accordance with Specific Condition and Limitation No. S-9.
- ▶ **Notifications and Reporting:** This permit requires notifications and reporting in accordance with Specific Condition and Limitation No. S-10.

- ▶ **Appendix A** contains information related to toxic air pollutant emissions at your facility. Please refer to General Condition and Limitation No. G-22 to comply with the air toxics requirement.
- ▶ **Appendix B** identifies insignificant activities at your facility. Some of these insignificant activities may have associated recordkeeping and reporting requirements.
- ▶ This Permit contains certain new or revised requirements including but not limited to monitoring of new control devices (Condition S-7) and a reference to your existing Risk Management Program (Condition S-4).
- ▶ This Permit is transferable to future owners and operators only through action of the Director of MCAQ and shall be subject to the conditions and limitations as specified therein.

If any new or revised parts, requirements, or limitations contained in this Permit are unacceptable to you, you have the right to a hearing before the Air Quality Commission upon written demand to the Director within thirty (30) days following receipt of this Permit. The hearing request must identify the specific issues to be contended as described in MCAPCO Regulation 1.5306 - "Hearings" Paragraph (b). Unless such demand is made, this Permit shall be final and binding.

If there are any questions regarding this matter, please do not hesitate to contact me at (704)336-5430.

Sincerely,



Donna Cavaliere  
Sr. Air Quality Specialist

DSC:smh

Enclosures (3)  
Permit No. 19-083-959  
Appendix A  
Appendix B



# AIR QUALITY PERMIT TO CONSTRUCT/OPERATE 19-083-959

In accordance with the provisions of the Mecklenburg County Air Pollution Control Ordinance,

**PERMISSION IS HEREBY GRANTED TO**

COMPANY NAME	FACILITY LOCATION
Sterigenics US, LLC	10821 Withers Cove Park Drive, Charlotte, North Carolina 28278

**FOR THE INSTALLATION AND OPERATION OF**

**An ethylene oxide sterilization process with associated air emission sources as listed in the emission source table.**

Sterigenics US, LLC shall be subject to the General and Specific Conditions and Limitations, Emission Limits, Monitoring Requirements, Reporting and Recordkeeping Requirements contained herein.

This Permit shall be effective from the date of its issuance unless modified or void/revoked.

Appendices A and B are included to provide information relevant to this Permit.

Jason Rayfield / 11-7-2019  
Air Quality Program Manager / Date

# EMISSION SOURCE TABLE

Facility Name: Sterigenics US, LLC

Facility Address: 10821 Withers Cove Park Dr., Charlotte, NC 28278

Permit to Construct/Operate No.: 19-083-959

Date Issued: November 7, 2019

Emission Source ID	Emission Source Description	Installation (I), Modification(M) Dates	Control Device (ID) or Method	Permitted Pollutant(s) Emitted from Emission Source	Applicable Specific Conditions and Limitations
ES- 1-6, ES- 13-15	Nine (9) Sterilizer Chambers (SC) with Vacuum Pumps (VP) including: ES-1, SC #1, 2,500 cubic feet, VP #1 ES-2, SC #2, 2,500 cubic feet, VP #2 ES-3, SC #3, 2,500 cubic feet, VP #3 ES-4, SC #4, 2,500 cubic feet, VP #4 ES-5, SC #5, 2,500 cubic feet, VP #5 ES-6, SC #6, 2,500 cubic feet, VP #6 ES-13, SC #7, 2,655 cubic feet, VP #7 ES-14, SC #8, 5,310 cubic feet, VP #8 ES-15, SC #9, 5,310 cubic feet, VP #9	1: I=1995, M=1999 2: I=1995, M=1999 3: I=1998, M=1999 4: I=1999 5: I=1999 6: I=1999 7: I=2002 8: I=2002 9: I=2002	<b>CD-2:</b> One (1) Advanced Air Technologies Packed-bed Acid Scrubber  - and -  <b>PO-1:</b> Polishing Dry Bed System- Two (2) bunks consisting of four (4) dry bed units I=2019	Ethylene Oxide VOC	S-1, S-2, S-3, S-4, S-5, S-6, S-7, S-8, S-9, S-10
BV- 1-6 BV- 13-15	Nine (9) Sterilizer Chamber Back Vents (BV) including: BV-1, BV #1 BV-2, BV #2 BV-3, BV #3 BV-4, BV #4 BV-5, BV #5 BV-6, BV #6 BV-13, BV #7 BV-14, BV #8 BV-15, BV #9	1: I=1995, M=1999 2: I=1995, M=1999 3: I=1998, M=1999 4: I=1999 5: I=1999 6: I=1999 7: I=2002 8: I=2002 9: I=2002	<b>CD-1:</b> One (1) Anguil Catalytic Oxidizer	Ethylene Oxide VOC	S-1, S-2, S-3, S-4, S-5, S-6, S-7, S-8, S-9, S-10

Emission Source ID	Emission Source Description	Installation (I), Modification(M) Dates	Control Device (ID) or Method	Permitted Pollutant(s) Emitted from Emission Source	Applicable Specific Conditions and Limitations
ES-11, ES-12, ES-16	Three Aeration Rooms (AR) ES-11, AR #1, 95,000 cubic feet ES-12, AR #2, 154,800 cubic feet ES-16, AR #5, 42,000 cubic feet	1: I=1997 2: I=1999 5: I=2010, M=2013	<b>CD-1:</b> One (1) Anguil Catalytic Oxidizer - or - <b>RCO-1:</b> One (1) Gulf Coast Environmental Systems Regenerative Catalytic Oxidizer -in series with- <b>NP-1:</b> Negative Pressure Dry Bed System- Twelve (12) bunks consisting of twenty-four (24) dry bed units I=2019	Ethylene Oxide VOC	S-1, S-2, S-3, S-5, S-6, S-7. S-8, S-9, S-10
IA-1	Indoor Air Capture System	I=2019	<b>NP-1:</b> Negative Pressure Dry Bed System- Twelve (12) bunks consisting of twenty-four (24) dry bed units I=2019	Ethylene Oxide VOC	S-3, S-5, S-7, S-9, S-10

# MECKLENBURG COUNTY AIR QUALITY

## Air Quality Permit Conditions and Limitations

Facility Name: Sterigenics US, LLC  
Facility Address: 10821 Withers Cove Park Drive, Charlotte, NC 28278  
Permit to Construct/Operate No.: 19-083-959

### GENERAL CONDITIONS AND LIMITATIONS

#### ADMINISTRATIVE

- G-1. The facility shall be operated in accordance with the Mecklenburg County Air Pollution Control Ordinance ("MCAPCO") including but not limited to the conditions specified herein and any other applicable State or Federal regulations.
- The provisions of this permit are severable. Upon any administrative or judicial challenge, or if any provision of this permit is held invalid, all permit requirements, except those being challenged, will remain valid and enforceable.
- G-2. Ownership of this permit is transferable to another party only by written approval by the Director. Application for ownership transfer shall be made by letter to the Director in accordance with **MCAPCO Regulation 1.5212 - "Applications"** and accompanied by the applicable fee.
- G-3. Compliance with MCAPCO, including the specific conditions herein, shall be determined by source testing, surveillance, visual observations, data review, plant inspections, and any other methods applicable to the facility.
- G-4. The facility shall be operated in accordance with **MCAPCO Regulation 1.5211 - "Applicability"**. An owner or operator shall have received a permit from Mecklenburg County Air Quality ("MCAQ") and shall comply with the conditions of such permit before constructing, modifying or operating any air pollution source or entering into a contract to construct or install any air cleaning device. This permit does not relieve the facility from the responsibility of acquiring any other permits that may be required.
- G-5. This permit and its conditions, unless otherwise stated, shall be applicable only to the items, processes and/or air pollution control equipment specifically enumerated herein.
- G-6. In accordance with **MCAPCO Regulation 1.5104 - "General Duties and Powers of the Director, With the Approval of the Board"**, the Director or his authorized representative may request performance testing of any emission source to ensure compliance.
- G-7. The owner or operator shall submit all reports or information as may be required by MCAQ.
- G-8. This permit may be revoked or modified as outlined in **MCAPCO Regulations 1.5232 - "Issuance, Revocation, and Enforcement of Permits"**, and **1.5231 - "Air Quality Fees"**. Instances which may result in such actions are as follows:
- A. Information submitted by the source on which this permit is based has been determined to be incorrect;
  - B. The regulations or conditions under which the permit was based change including but not limited to changes in surrounding land use and/or surrounding population and/or documented advances in scientific, medical or technical knowledge;
  - C. Violations of permit conditions listed herein;

- D. Construction of the permitted equipment does not commence within 18 months of permit issuance or once construction has begun it ceases prior to completion for a period of 18 consecutive months;
- E. Operation of a permitted facility or process ceases permitted activities for a period of 18 consecutive months;
- F. Failure to pay the annual administering and compliance monitoring fee within 60 days after being billed;
- G. Refusal by the permittee to allow the Director or his authorized representative to enter the permittee's premises where a source of emissions is located, have access to records required to be kept under the terms and conditions of the permit, inspect any source of emissions, control equipment, and any monitoring equipment or method required in the permit or sample any emission source at the facility.
- H. Failure to pay a civil penalty within 20 days after the date that the permittee has been notified that the civil penalty has been finally assessed under **MCAPCO Regulation 1.5304**.

- G-9. Violation of any applicable MCAPCO regulation or condition listed herein could result in administrative fines and/or legal action as prescribed in **MCAPCO Section 1.5300 - "Enforcement; Variances; Judicial Review"**.
- G-10. The facility shall be operated in accordance with **MCAPCO Regulation 1.5211 - "Applicability"**, such that all activities exempted from permit requirements and/or not specifically listed on this permit shall still comply with any applicable requirement in MCAPCO.
- G-11. In accordance with **MCAPCO Regulation 1.5219 - "Retention of Permit at Permitted Facility"**, a copy of this permit shall be retained at the facility.
- G-12. The facility shall be operated in accordance with **MCAPCO Regulation 2.0304 - "Preplanned Abatement Program"**. A plan to reduce the emissions of air pollutants into the outdoor atmosphere during periods of an air pollution episode shall be prepared as required. The plan shall be consistent with good industrial practices and safe operating procedures, shall address varying degrees of hazard identified as air pollution alert, air pollution warning and air pollution emergency, and shall be made available to MCAQ within 30 days of such request.

**OPERATIONAL**

- G-13. The facility shall be operated in accordance with **MCAPCO Regulation 1.5214 - "Commencement of Operation"**. Upon completion of construction, alteration or installation pursuant to this permit, the permit holder shall notify the Director in writing of the completion date and the holder's intent to commence operation.
- G-14. The facility shall be operated in accordance with **MCAPCO Regulation 2.1110 - "National Emission Standards for Hazardous Air Pollutants"**, which refers to Title 40 of the Code of Federal Regulations Part 61.140 to 61.157, Subpart M, National Emission Standard for Asbestos, when conducting any renovation or demolition activities.
- G-15. All facilities that produce, process, handle, or store hazardous materials have a general duty, as required under **Section 112(r)(1)** of the Clean Air Act (commonly referred to as the General Duty Clause), to prevent the accidental release and to minimize the consequences of any such release of these substances. In addition, the Chemical Accident Prevention Provisions of **40 CFR Part 68** and **MCAPCO Regulation 2.2100 - "Risk Management Program"** apply to any stationary source owner or operator that has more than a threshold quantity of a regulated substance in a process, as determined under **40 CFR Part 68.115**. The requirement includes, but is not limited to, the submittal of a Risk Management Plan. A Risk Management Plan is required to be submitted by the date on which a regulated substance is first present above a threshold quantity. For applicability provisions, refer to **40 CFR Part 68.10**. For a list of regulated substances, refer to **40 CFR Part 68.130**.

- G-16. The facility shall be operated in accordance with **MCAPCO Regulation 1.5107 - "Control and Prohibition of Visible Emissions"**, such that visible emissions shall not be more than 20% opacity for an aggregate of more than six (6) minutes in any one hour or more than twenty (20) minutes in any 24-hour period. Facilities subject to a visible emission standard as specified by applicability to **MCAPCO Regulations 2.0508, 2.0524, 2.1110, or 2.1111**, shall comply with the more stringent standard. In no case shall any source's visible emissions exceed 20% opacity.
- G-17. The facility shall be operated in accordance with **MCAPCO Regulation 1.5108 - "Dust and Related Material"**, such that dust shall not be discharged into the atmosphere in such quantities that the ambient air quality standards are exceeded at the property line or in such quantities or of such toxic or corrosive nature that may be injurious to humans or animals or may cause damage to the property of others.
- G-18. As required by **MCAPCO Regulation 2.0540 - "Particulates from Fugitive Dust Emission Sources"**, the permittee shall not cause or allow fugitive dust emissions to cause or contribute to substantive complaints.
- A. If fugitive dust emissions cause or contribute to substantive complaints, the permittee shall:
- (1) within 30 days upon receipt of written notification from the Director of a second substantive complaint in a 12-month period, submit to the Director a written report that includes the identification of the probable source(s) of the fugitive dust emissions causing complaints and what immediate measures can be made to abate the fugitive emissions;
  - (2) within 60 days of the initial report submitted under Subparagraph (1) of this Paragraph, submit to the Director a control plan as described in Paragraph (f) of this Regulation; and
  - (3) within 30 days after the Director approves the plan, be in compliance with the plan.
- B. The Director may require that the permittee develop and submit a fugitive dust control plan as described in MCAPCO 2.0540(f) if:
- (1) ambient air quality measurements or dispersion modeling as provided in Paragraph (e) of **MCAPCO Regulation 2.1106 - "Determination of Ambient Air Concentrations"** show violation or potential for a violation of an ambient air quality standard for particulates in MCAPCO Section 2.0400 - "Ambient Air Quality Standards"; or
  - (2) if MCAQ observes excessive fugitive dust emissions from the facility beyond the property boundaries for six minutes in any one hour using Reference Method 22 in 40 CFR 60, Appendix A
- G-19. The facility shall be operated in accordance with **MCAPCO Regulation 1.5109 - "Nuisance"**. The source shall not discharge any air contaminants or other material to cause injury, detriment, nuisance, annoyance, or endanger the comfort, repose, health or safety of public or property.
- G-20. Sources not regulated under **MCAPCO Regulations 2.0524 and 2.1110** shall be operated in accordance with **MCAPCO Regulation 2.0535 - "Excess Emissions Reporting and Malfunctions"** and **2.0605 - "General Recordkeeping and Reporting Requirements"**, and satisfactorily demonstrate to MCAQ that any excess emissions are the result of a malfunction, or the result of start-up or shut down and were unavoidable. The facility shall notify MCAQ of the occurrence of any excess emission lasting more than four hours and which result from a malfunction, a breakdown of process or control equipment or any other abnormal conditions as soon as practical but in all cases by 9:00 AM Eastern time of MCAQ's next business day after becoming aware of the occurrence.
- G-21. **Odorous Emissions**
- The facility shall be operated in accordance with **MCAPCO Regulation 1.5110 - "Control and Prohibition of Odorous Emissions"**. The owner or operator of a facility shall not operate the facility without implementing management practices or installing and operating odor control equipment sufficient to prevent odorous emissions from the facility from causing or contributing to objectionable odors beyond the facility's boundary.

If the Director determines that a source or facility is emitting an objectionable odor, the owner or operator shall be responsible for:

- providing the maximum feasible control determination according to the procedures in **MCAPCO Regulation 1.5113 - “Determination of Maximum Feasible Controls for Odorous Emissions”**, and
- implementing maximum feasible controls for the control of odorous emissions.

G-22. In accordance with **MCAPCO Section 1.5700 - “Toxic Air Pollutant Procedures”** and/or **Regulation 2.1104 - “Toxic Air Pollutant Guidelines”**, the toxic air pollutants (“TAP”) emitted by existing processes have been reviewed for regulatory applicability by MCAQ. If applicable, an Appendix A lists the associated TAPs.

In accordance with **MCAPCO Regulations 1.5111 - “General Recordkeeping: Reporting: Monitoring Requirements”**, **2.0605 - “General Recordkeeping and Reporting Requirements”**, and/or **2.0903 - “Recordkeeping: Reporting: Monitoring”**, the facility shall report any process additions, modifications or deletions which affect the emissions of any TAP listed in **MCAPCO Regulation 1.5711 - “Emission Rates Requiring a Permit”**, as prescribed by the following:

- A. If the process modifications will result in a facility-wide TAP emission rate that exceeds the rate listed in **MCAPCO Regulation 1.5711** for any TAP, apply and receive an air toxics permit before the process modification occurs; or
- B. If the process modifications will result in facility-wide TAP emission rates that are below the rates listed in **MCAPCO Regulation 1.5711**, submit the new emission rates to MCAQ 15 days prior to the initial change; or
- C. If the process modifications will not result in a net TAP emission increase, provide MCAQ with demonstration (15 days prior to the initial change) that the proposed modification will not result in a net TAP emission increase at the facility.

The facility is required to maintain documentation such that upon request by MCAQ, the facility can make a demonstration that facility-wide emissions of TAPs have or have not exceeded the rates listed in **MCAPCO Regulation 1.5711**.

### **SPECIFIC CONDITIONS AND LIMITATIONS**

#### **PROCEDURAL**

S-1. Permit No. 14-017-959 issued on April 8, 2014, shall be void upon issuance of this Permit.

#### **EMISSION STANDARDS**

S-2. The facility shall be operated in accordance with **MCAPCO Regulation 2.1111 - “Maximum Achievable Control Technology”** and **40 CFR Part 63 - “National Emission Standards For Hazardous Air Pollutants For Source Categories”**. The requirements are stated in **40 CFR 63.1 to 63.15 Subpart A - “General Provisions”**, and **40 CFR 63.360 to 63.368, Subpart O - “Ethylene Oxide Emissions Standards for Sterilization Facilities”**, which include the following pertinent sections:

A. **63.360-“Applicability”**

*Ethylene oxide sterilization and/or ethylene oxide fumigation facilities are subject to this Regulation by category.*

B. **63.361-“Definitions”**

C. **63.362-“Standards”**

*Portions of this section require that:*

- (1) *Each owner or operator of a sterilization source using 1 ton shall reduce ethylene oxide emissions to the atmosphere by at least 99 percent from each sterilization chamber vent.*

- (2) *Each owner or operator of a sterilization source using 10 tons shall reduce ethylene oxide emission to the atmosphere from each aeration room vent to a maximum concentration of 1 ppmv or by at least 99 percent, whichever is less stringent, from each aeration room vent.*
- (3) *Each owner or operator of a sterilization source using 10 tons shall either reduce ethylene oxide emissions to the atmosphere by at least 99 percent by manifolded emissions from each chamber exhaust vent to a control device used to comply with 40 CFR 63.362 (c) or (d) or shall comply with 40 CFR Paragraph 63.362(e) by reducing ethylene oxide emissions by at least 99 percent from each chamber exhaust vent (without manifolded).*

**D. 63.363-“Compliance and Performance Provisions”**

*Refer to 63.363 and Condition and Limitation No. S-9 of this Permit for all testing requirements. Refer to 63.364 and Condition and Limitation Nos. S-6 and S-7 of this Permit for all operating limits. Portions of section 63.363 require that:*

- (1) *For facilities with acid-water scrubbers, the owner or operator shall establish as an operating limit the maximum liquor tank level using the procedures described in 63.365(e)(2).*
- (2) *For facilities with catalytic oxidizers, the operating limit consists of the recommended minimum oxidation temperature provided by the oxidation unit manufacturer for an operating limit.*
- (3) *Facilities with catalytic oxidizers shall comply with one of the following work practices:*
  - a. *once per year after the initial compliance test, conduct a performance test during routine operations, i.e., with product in the chamber using the procedures described in 63.365(b) or (d) as appropriate. If the percent efficiency is less than 99 percent, restore the catalyst as soon as practicable but no later than 180 days after conducting the performance test; or*
  - b. *once per year after the initial compliance test, analyze ethylene oxide concentration data from 63.364(e) or a continuous emission monitoring system (CEMS) and restore the catalyst as soon as practicable but no later than 180 days after data analysis; or*
  - c. *every five (5) years, beginning 5 years after the initial compliance test (or by December 6, 2002, whichever is later), replace the catalyst bed with new catalyst material.*
- (4) *For facilities with a control technology other than acid-water scrubbers or catalytic or thermal oxidizers, the owner or operator of the facility shall provide to the Administrator or delegated authority information describing the design and operation of the air pollution control system, including recommendations for the operating parameters to be monitored to demonstrate continuous compliance. Based on this information, the Administrator will determine the operating parameter(s) to be measured during the performance test. During the performance test required in paragraph (a) of this section, using the methods approved in §63.365(g), the owner or operator shall determine the site-specific operating limit(s) for the operating parameters approved by the Administrator.*

**E. 63.364-“Monitoring Requirements”**

*Refer to 63.364 and Condition and Limitation No. S-7 of this Permit for all monitoring requirements.*

**F. 63.365-“Test Methods and Procedures”**

**G. 63.366-“Reporting Requirements”**

*Refer to 63.366 and Condition and Limitation No. S-10 of this Permit for all reporting requirements.*

**H. 63.367-“Record Keeping Requirements”**

*Refer to 63.10, 63.367 and Condition and Limitation No. S-7 of this Permit for all record keeping and reporting requirements.*

**I. 63.368-“Implementation and enforcement.”**

- S-3. The source shall be operated in accordance with **Mecklenburg County Air Pollution Control Ordinance (“MCAPCO”) Regulation 2.0538 - “Control of Ethylene Oxide Emissions”**.

Facilities subject to this Regulation shall comply with the following standards:

- (1) For sterilization chamber evacuation, a closed loop liquid ring vacuum pump, or equipment demonstrated to be as effective at reducing emissions of ethylene oxide shall be used;
- (2) For sterilizer exhaust, a reduction in the weight of uncontrolled emissions of ethylene oxide of at least 99.8 percent by weight shall be achieved;
- (3) For sterilizer unload and backdraft valve exhaust, a reduction:
  - (A) in uncontrolled emissions of ethylene oxide of at least 99 percent by weight shall be achieved; or,
  - (B) to no more than one part per million by volume of ethylene oxide shall be achieved.
- (4) Sterilized product ethylene oxide residual shall be reduced by:
  - (A) a heated degassing room to aerate the products after removal from the sterilization chamber; the temperature of the degassing room shall be maintained at a minimum of 95° Fahrenheit during the degassing cycle, and product hold time in the aeration room shall be at least 24 hours; or,
  - (B) a process demonstrated to be as effective as Part (d)(4)(A) of this Regulation.
- (5) Emissions of ethylene oxide from the degassing area (or equivalent process) shall be vented to a control device capable of reducing uncontrolled ethylene oxide emissions by at least 99 percent by weight or to no more than one part per million by volume of ethylene oxide. The product aeration room and the product transfer area shall be maintained under a negative pressure.

S-4. The facility shall be operated in accordance with **MCAPCO Regulation 2.2100 - "Risk Management Program"**. The requirements are stated in **40 CFR 68.1 to 68.220 - "Chemical Accident Prevention Provisions"** which includes the following subparts:

**A. Subpart A – "General"**

*Portions of this subpart require an owner or operator of a stationary source that has more than a threshold quantity of a regulated substance in a process to comply with the requirements of this part three years after the date on which a regulated substance is first listed under §68.130 or the date on which a regulated substance is first present above a threshold quantity in a process, whichever is later.*

**B. Subpart B – "Hazard Assessment"**

*Portions of this subpart require that an owner or operator shall prepare worst-case release and alternative release scenario analyses, complete the 5 year accident history and conduct an offsite consequence analysis as described in the applicable sections of §68.20 through 68.42. The offsite consequence analysis shall be reviewed and updated at least every five years, or as process changes necessitate, in accordance with §68.36.*

**C. Subpart C – "Program 2 Prevention Program"**

*Portions of this subpart require that sources subject to the Program 2 Prevention Program comply with safety information, hazard review, operating procedures, training, maintenance, compliance audits, and incident investigation requirements in accordance with §68.48 through §68.60.*

**D. Subpart D – "Program 3 Prevention Program"**

*Portions of this subpart require that sources subject to the Program 3 Prevention Program comply with process safety information, process hazards analysis, operating procedures, training, mechanical integrity, management of change, pre-startup review, compliance audits, incident investigation, employee participation, hot work permit, and contractors requirements in accordance with §68.65 through §68.87.*

**E. Subpart E – "Emergency Response"**

*Portions of this subpart require that affected sources develop and implement an emergency response program for the purpose of protecting public health and the environment, in accordance with §68.90 through §68.95.*

**F. Subpart F – “Regulated Substances for Accidental Release Prevention”**

*Portions of this subpart designate regulated substances for a Risk Management Plan (RMP), threshold quantities and determination, and establish petition requirements to add or delete substances.*

**G. Subpart G – “Risk Management Plan”**

*Portions of this subpart require:*

- (1) An owner or operator submit to EPA a single RMP that includes the information required by §68.155 through §68.185 for all covered processes.*
- (2) The RMP shall be reviewed and updated at least once every five years in accordance with §68.190.*
- (3) Emergency contact information shall be updated within one month of any change in accordance with §68.195.*
- (4) New accident history information shall be updated for any accidental release meeting the five-year accident history reporting criteria within six months of the release in accordance with §68.195.*

**H. Subpart H – “Other Requirements”**

*This subpart covers record retention, information availability to the public, permit requirements, and audits.*

**EMISSION LIMITS**

S-5. The facility shall be operated in accordance with **MCAPCO Regulation 1.5236 - “Synthetic Minor Facilities”**, such that facility-wide emissions during any consecutive 12-month period shall be less than:

- ▶ 100 tons for Volatile Organic Compounds (VOCs); and,
- ▶ 10 tons for any hazardous air pollutant (HAP) which has been listed pursuant to Section 112(b) of the Clean Air Act, and 25 tons of any combination of such HAPs.

Emissions for the above-referenced pollutant(s) shall be determined using one or more of the following methods as applicable:

1. Emission rates and control efficiencies obtained through MCAQ-approved emission source testing;
2. Material (mass) balance based on product usage;
3. Emission factors or rates found in the latest edition of the “Compilation of Air Pollutant Emission Factors”, EPA document AP-42;
4. Other emission factors or rates as approved by MCAQ.

Air emissions emanating from activities exempted from permitting pursuant to **MCAPCO Regulation 1.5211 - “Applicability”** subparagraph (g)(2) shall be considered when determining compliance with facility wide limits. The emissions limitation was requested by the facility to preclude a categorical determination as a “major facility” and the requirements of **MCAPCO Section 1.5500 - “Title V Procedures”** and/or **Section 2.0900 – “Volatile Organic Compounds.”**

S-6. In accordance with **40 CFR 63.363 - “Compliance and Performance Provisions”**:

- (1) The Advanced Air Technologies scrubber (CD-2) shall be operated in such a manner as to not exceed the liquor tank maximum level as established by a single measurement of the liquor tank during the most recently approved performance test. See Attachment 1 for the maximum liquor tank level.
- (2) For the Anguil catalytic oxidizer (CD-1), the oxidation temperature shall be greater than or equal to the minimum temperature of 300° F as recommended by the oxidation unit manufacturer.
- (3) For the Gulf Coast Environmental Systems regenerative catalytic oxidizer (RCO-1), the oxidation temperature shall be greater than or equal to the minimum temperature of 600° F as recommended by the oxidation unit manufacturer.
- (4) The Negative Pressure dry bed system (NP-1), shall be operated in accordance with the Administrator-recommended parameters as outlined in 40CFR 63.363(e). See Attachment 1 for parameter values.

### **MONITORING AND RECORDKEEPING REQUIREMENTS**

S-7. In accordance with MCAPCO Regulations 1.5111 - “General Recordkeeping, Reporting and Monitoring Requirements” and 2.0605 – “General Recordkeeping and Reporting Requirements” the facility shall monitor and record the following operating parameters for the emission sources and/or control devices as listed below:

EMISSION SOURCE / CONTROL DEVICE	OPERATING PARAMETER	PARAMETER RANGE	MINIMUM MONITORING FREQUENCY (Once per...)
CD-1: Anguil Catalytic Oxidizer	Catalyst Outlet Temperature <sup>1, 3</sup>	≥ 300°F	monitor and record continuously
	Flow Rate of the VOC Stream Through the Combustion Chamber	8,000 - 12,500 ft <sup>3</sup> /min	monitor and record continuously
	Pressure Drop Across the Catalyst Bed	8.0-18.0 inches H <sub>2</sub> O	monitor continuously and record once per day
CD-2: AAT Acid Scrubber	Static pressure drop across scrubber	0.0-6.0 inches H <sub>2</sub> O	monitor continuously and record once per week
	Total liquid flow rate to scrubber	220-450 gallons/min.	monitor continuously and record once per week
	Recirculation liquid pH	0.1-2.0 pH	monitor and record once per week
	Liquor Tank Level <sup>2</sup>	(See Attachment 1)	monitor and record once per week
RCO-1: GCES Regenerative Catalytic Oxidizer	Catalyst Temperature <sup>3</sup>	≥ 600 °F	monitor and record continuously
	Flow Rate of the VOC Stream Through the Combustion Chamber <sup>2</sup>	(See Attachment 1)	monitor and record continuously
	Pressure Drop Across the Catalyst Bed	(See Attachment 1)	monitor continuously and record once per day
NP-1: Negative Pressure Dry Bed System	Ethylene Oxide concentration at outlet	< 1 ppm or reduction of ≥ 99%	monitor and record once per week
	EPA Administrator-recommended parameter to be determined	(See Attachment 1)	(See Attachment 1)
PO-1: Polishing Dry Bed System	Ethylene Oxide concentration at outlet	< 1 ppm or reduction of ≥ 99%	monitor and record once per week
Three (3) Aeration Rooms: (ES-11, ES-12, ES-16)	Room temperature	≥ 95°F during the degassing cycle	monitor continuously and record once per day
	Product hold time	≥ 24 hours	

- 1 From 15-minute or shorter period temperature values, a data acquisition system for the temperature monitor shall compute and record a daily average oxidation temperature. Strip chart data shall be converted to record a daily average oxidation temperature each day any instantaneous temperature recording falls below the minimum temperature.
- 2 Minimum/maximum values (as appropriate) for these operational parameters are stated in Attachment 1.
3. The facility shall install, calibrate, operate, and maintain a temperature monitor accurate to within ±5.6 °C (±10 °F) to measure the oxidation temperature as outlined in 40 CFR 63.364(c)(4),

The facility shall maintain the above-specified operating records as well as any maintenance records for activity conducted on the equipment for a period of not less than 5 years, unless otherwise specified by the permit. The records shall be available for inspection by MCAQ personnel upon request.

- S-8. The sterilization chambers, vacuum pumps, back vents, and aeration rooms shall be operated concurrently with the associated control device(s) specified in this Permit to Construct/Operate except when subject to the malfunction provisions contained in **40 CFR 63.360 to 63.368, Subpart O - "Ethylene Oxide Emissions Standards for Sterilization Facilities"**. The facility shall be properly operated and maintained at all times in a manner that will effect an overall reduction in air pollution.

**PERFORMANCE TESTING REQUIREMENTS**

- S-9. The facility shall, at its own expense and using the most recent versions of the performance test methods contained in 40 CFR Part 60 (Appendix A) or Part 63 or as approved by the Administrator of the USEPA or MCAQ, demonstrate compliance with the appropriate regulatory requirement as follows:

EMISSION SOURCE / CONTROL DEVICE DESCRIPTION AND ID	DEMONSTRATE COMPLIANCE WITH...	SCHEDULED TESTING FREQUENCY
Sterilizer Chambers / Vacuum Pumps with AAT scrubber and Polishing dry bed control devices (CD-2 in series with PO-1) Back Vents with Anguil Oxidizer control device (CD-1) Aeration Rooms with Anguil Oxidizer control device (CD-1) Aeration Rooms with Gulf Coast Oxidizer and Negative Pressure dry bed control devices (RCO-1 in series with NP-1) Indoor Air Capture System with Negative Pressure dry bed control device (NP-1)	<b>MCAPCO Regulation 2.0538 - "Control of Ethylene Oxide Emissions"</b>	<ul style="list-style-type: none"> <li>• within 180 days after initial startup of the emission source or following any modification to the emission source or control device</li> <li>• additional tests upon written request by MCAQ or as requested by Permittee</li> </ul>
<b>40 CFR 63 Subpart O</b> emissions sources	Refer to <b>40 CFR 63.7, 63.363, 63.365</b> and <b>Specific Condition and Limitation S-2</b> of this permit for specific testing requirements related to <b>40 CFR 63</b> emission sources	Refer to <b>40 CFR 63.7, 63.363</b> and <b>63.365</b>

All performance tests shall be made by, or under the direction of, a person qualified by training and/or experience in the field of air pollution testing and shall be conducted in accordance with **MCAPCO Section 2.2600 - "Source Testing."** MCAQ shall be notified at least 60 days in advance of the proposed performance test so that it may have a representative present to observe the test at its option. The notification shall include a detailed description of the performance test procedures so that MCAQ may review and approve them. The final performance test results shall be submitted to MCAQ for review within 60 calendar days after completion of on-site testing. The performance test(s) specified in this condition do not preclude MCAQ from requesting performance testing for other emission sources or for other purposes as defined in **MCAPCO Regulation 1.5104 - "General Duties and Powers of the Director, With the Approval of the Board"**, and referenced in General Condition and Limitation No. G-6 of this Permit.

**NOTIFICATION AND REPORTING REQUIREMENTS**

- S-10. The facility shall be operated in accordance with **MCAPCO Regulations 1.5111 - “General Recordkeeping, Reporting and Monitoring Requirements”, 2.0605 – “General Recordkeeping and Reporting Requirements”, and/or 2.0903 - “Recordkeeping: Reporting: Monitoring”** and **MCAPCO Regulation 1.5236 - “Synthetic Minor Facilities”**, such that the following specific reports and/or notifications shall be submitted to MCAQ by the specified dates:

**(1) NOTIFICATIONS TO MCAQ**

POLLUTANT/ PARAMETER	NOTIFICATION REQUIREMENT	SUBMITTAL DATE
40 CFR 63 Subpart O emission sources	Refer to <b>40 CFR 63.9</b> and <b>63.366</b> and <b>Specific Condition and Limitation S-2</b> of this permit for all notification requirements.	Refer to <b>40 CFR 63.9</b> and <b>63.366</b>
	Refer to <b>40 CFR 63.363(e)</b> and <b>63.365(g)</b> for specific notification requirements related to alternative control methods	Refer to <b>40 CFR 63.363(e)</b> and <b>63.365(g)</b>
Performance test notification report	Detailed description of the proposed test procedures to be used on the ethylene oxide sterilization process	60 days prior to proposed test date
VOC HAP	Submit notification upon exceedance of the synthetic minor emission limitations specified in <b>Specific Condition and Limitation No. S-5</b> .	Within 2 business days of the exceedance discovery

**(2) REPORTS TO MCAQ**

POLLUTANT/ PARAMETER	REPORTING REQUIREMENT	EMISSION PERIOD (For previous)	SUBMITTAL DATES (Postmarked by)
VOC Ethylene Oxide	A report of facility-wide emissions (in tons) emanating from the emission sources listed on this permit to include, at a minimum, the following information: 1. Emission calculations including all supporting documentation. <i>(Calculations for previously submitted periods do not need to be re-submitted)</i> 2. Amount of ethylene oxide used	Calendar Year <i>(shall be tracked in rolling 12-month periods)</i>	April 30 of following year
40 CFR 63 Subpart O emission sources	Refer to <b>40 CFR 63.10</b> and <b>63.366</b> and <b>Specific Limitation and Condition No. S-2</b> of this permit for all specific reporting requirements	Refer to <b>40 CFR 63.10</b> and <b>63.366</b>	Refer to <b>40 CFR 63.10</b> and <b>63.366</b> . Requirements include: Semiannual Compliance Reports for Periods: • January 1 – June 30, due July 30th of each calendar year. • July 1 – December 31, due January 30th of each calendar year.
Performance Test Report	Results of Performance Test Conducted	Not applicable	Within 60 days after test
Appendix B : Insignificant Activities	Refer to Appendix B: Insignificant Activities Table for additional recordkeeping and reporting requirements.		



## APPENDIX A: TOXIC AIR POLLUTANT REVIEW

*Facility Name: Sterigenics US, LLC*

*Facility Address: 10821 Withers Cove Park Dr., Charlotte, NC 28278*

*Date Issued: November 7, 2019*

The facility has been reviewed for toxic air pollutant emissions under MCAPCO Regulation 1.5700 - "Toxic Air Pollutant Procedures" and been found to emit the following substances:

Reviewed Toxic Air Pollutant (TAP)	CAS No.	Is TAP also a Hazardous Air Pollutant (HAP)?	Last Reviewed (Permit Number)	Compliance Demonstration	
				Are Actual Emissions Above TPER? <sup>1</sup>	Model or Avoidance Limit?
ethylene oxide	75-21-8	Y	19-083-959	N/A <sup>2</sup>	N/A

1. The toxic air pollutant permitting emission rates (TPER) for each TAP can be found in MCAPCO Regulation 1.5711 - "Emission Rates Requiring a Permit". The applicable TPER values depend on release point type and stack characteristics.
2. Ethylene oxide used for sterilization is exempt under MCAPCO 1.5702 - "Exemptions", Subparagraph (a)(29).



## APPENDIX B: INSIGNIFICANT ACTIVITIES TABLE

Facility Name: Sterigenics US, LLC

Facility Address: 10821 Withers Cove Dr., Charlotte, NC 28278

Date Issued: November 7, 2019

### INSIGNIFICANT ACTIVITIES DUE TO SIZE AND PRODUCTION RATE

Operation of the following processes/equipment are exempted from permitting pursuant to MCAPCO Regulation 1.5211 - "Applicability" Subparagraph (g)(2), but are considered when determining compliance with facility-wide limits. For facilities with facility-wide emission limits, recordkeeping and reporting may be required, as listed below, pursuant to MCAPCO Regulation 1.5104 - "General Duties and Powers of the Director, With the Approval of the Board" and 1.5236 - "Synthetic Minor Facilities."			
Process/Equipment	Exemption Reference and Explanation	Recordkeeping/Reporting Requirements	Submittal Date (No Later Than...)
One (1) 4.5 mmBtu/hr Cleaver Brooks boiler, fueled exclusively by natural gas	MCAPCO 1.5211 Subpart (g)(2)(B)(ii): fuel combustion equipment exclusively fired by natural gas with a heat input rating less than 65 million Btu/hr	A report of combustion emissions from the emission sources listed in this Table, including:  1. All supporting documentation, including emission calculations, and; 2. Natural gas usage (in cubic feet)	April 30 of the following year
Two (2) 0.76 mmBtu/hr Parker hot water boilers, fueled exclusively by natural gas			
One (1) 3.348 mmBtu/hr York Shipley steam boiler, fueled exclusively by natural gas (I=2014)			
Two (2) 0.25 mmBtu/hr Reznor heaters, fueled exclusively by natural gas			

### INSIGNIFICANT ACTIVITIES DUE TO CATEGORY

Operation of the following processes/equipment are exempted from permitting pursuant to MCAPCO Regulation 1.5211 - "Applicability" Subparagraph (g)(1). There are no recordkeeping or reporting requirements associated with these activities.	
Process/Equipment	Exemption Reference and Explanation
Post-Aeration Dock Area	MCAPCO 1.5211, Subpart (g)(1)(K)(x): no applicable requirements

### ACTIVITIES EXEMPTED DUE TO FACILITY POTENTIAL

Operation of the following processes /equipment are exempted from permitting for the pollutant(s) indicated pursuant to MCAPCO Regulation 1.5211 - "Applicability" Paragraph (f). Facility-wide potential emissions of the listed pollutant are less than five tons annually. There are no recordkeeping or reporting requirements associated with these pollutants.	
Process/Equipment	Pollutant Emitted
None	



## ATTACHMENT 1: Operational Parameters

*Facility Name: Sterigenics US, LLC.*

*Facility Address: 10821 Withers Cove Park Dr., Charlotte, NC 28278*

*Date Issued: November 7, 2019*

Control Device	Operating Parameter	Established Value <sup>1</sup>	Applicable Test Date <sup>2</sup>
RCO-1: GCES Regenerative Catalytic Oxidizer	Flow Rate of the VOC Stream Through the Combustion Chamber	TBD	TBD
	Pressure drop across the catalyst bed	TBD	TBD
CD-2: Advanced Air Technologies Scrubber	The maximum liquor tank level	328 inches (27'4")	November 15-16, 2007
NP-1: Negative Pressure Dry Bed System	Administrator recommended parameters TBD	TBD	TBD

Notes:

1. Operating parameters to be established during stack testing.
2. The "applicable test date" reflects the date of the most recent stack test that the operating parameter was established.

